Innovative Method for Amplatzer Device Implantation in Patients With Bronchopleural Fistulas

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Research article

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Abstract

Background: Bronchopleural fistula (BPF) is a relatively rare complication after various types of pulmonary resection. The double-sided mushroom-shaped occluder (Amplatzer device, AD) has been gradually used for BPF blocking due to its reliable blocking effect. We have improved the existing AD implantation methods to facilitate clinical use and named the new approach the Sheath-free method (SFM the aim of the present report was to explore the reliability and advantages of SFM for AD implantation.

Methods: We improved the existing placement methods by abandoning the sheath of the AD and using the working channel of the bronchoscope to directly store or release the AD without the use of general anesthesia, rigid bronchoscopy, fluoroscopy, or bronchography. A total of 6 patients (5 men and 1 woman, aged 66.67 ± 6.19 years [mean $\pm$ SD]) had bronchopleural fistulas sealed using the SFM for AD implantation.

Results: Closure was successfully performed in all 6 patients with the SFM, and the average duration of operation was 16.17 minutes (16.17 ± 4.67 minutes [mean $\pm$ SD]). Five patients achieved complete occlusion after the operation, and 1 patient who had multiple fistulas did not. No patients died due to operation complications and BPF recurrence. The average follow-up time was 13.2 months (range: 10-17 months).

Conclusion: We observed that the SFM for AD implantation—with accurate device positioning and a clear field of vision—is efficient and convenient. The AD is effective in BPF sealing, and patient symptoms significantly improved after sealing.

Background

Bronchopleural fistula (BPF) is a serious complication that occurs after various types of pulmonary resection. The incidence of BPF following surgery is 4.4%~8.0%^{1,2}, and BPF results in substantial economic and spiritual burden for patients^{3,4}. Risk factors⁵ include preoperative neoadjuvant chemotherapy, operations on the right side, and complete pneumonectomy. Once the complication appears, it is often difficult to treat, and the mortality rate ranges from 18–50%^{3,4}.

BPF is based on comprehensive treatment, including closed thoracic drainage, prolonged antibiotic use, symptomatic supportive treatment, and various fistula blocking methods⁶. Several studies have found that blocking BPF by means of respiratory endoscopy has the advantages of high patient acceptance, low operation risks, low overall costs, and rapid postoperative recovery^{7,8}. Endoscopic interventional treatment for BPF currently utilizes two major methods: one is to stimulate the formation of local granulation tissue and scar tissue through various kinds of physical and chemical methods to achieve a blocking effect; the other is to place various types of occluders, including distally closed metal stents, distally closed silicone stents, EBVs(Endobronchial Valves), and Amplatzer devices^{9–12}.

Fruchter O first reported the use of double-sided mushroom umbrella occluders (Amplatzer devices, ADs) or arterial catheter occlusion devices (Amplatzer vascular plugs, AVPs) in treating BPFs^{13–15}. Different methods for AD implantation have been reported in previous studies. According to Fruchter O, ADs are implanted under direct bronchoscopic and fluoroscopic visualization with the use of guide wires passed through the fistula as aids^{15,16}. In China, the common method of placement is using rigid bronchoscopy, or ADs are implanted via tracheal

intubation with the guidance of bronchoscopy passed through the nasal passage. In the current study, we describe a novel and innovative method (SFM) for AD implantation which makes AD implantation more convenient and effective in clinical use.

Methods

ADs (Fig. 1) are self-expanding double-sided mushroom umbrella structures woven from nickel-titanium alloy wires with a slender waist in the middle. In this study, we used the Amplatzer devices (VISEE medical Co; Shandong, China). Their sealing disc diameters range from 12 mm to 56 mm, and waist diameters range from 4 mm to 38 mm. We often selected models with waist diameters between 6 mm to 12 mm. The current procedure was carried out at the bronchoscopy operating room in patients under moderate sedation unless they were already mechanically ventilated. Patients received topical anesthesia with lidocaine, dextromethorphan and remifentanyl continuously administered for maintenance. After sedation, bronchoscopy was used to evaluate fistulas and select the AD model.

The innovation in SFM is the use of a bronchoscopy working channel to replace the sheath tube of the AD. An Olympus T series endoscopy (model Bf-it290, outer diameter of 5.9 mm and a working channel of 2.8 mm, Olympus Corp, Tokyo, Japan) was selected for implantation. The guide wire (diameter of 1.9 mm) was inserted into the working channel of the bronchoscope. After it extended out of the working channel, it was connected to the AD, so that the AD can be received or released by drawing the guide wire. The release process was performed directly under the bronchoscope, with a clear field of vision, and it could be adjusted by drawing the guide wire at any time until it was satisfactory. Upon reaching a satisfactory position, the device was detached. The bronchoscope were removed from the airway, and the patient was transferred to the recovery room. The device can be placed through the nasal passage, a tracheal tube, a laryngeal mask, or a rigid bronchoscopy depending on the patient's personal circumstances. Figures of procedures are presented in Fig. 2.

Results

In total, 6 patients (5 men and 1 woman, aged 66.67 ± 6.19 years [mean $\pm$ SD]) were treated in our center with bronchoscopy AD implantation between October 2018 and May 2019. The main etiology for BPF was pneumonectomy ($n = 3$) or lobectomy ($n = 3$). The underlying disease was primary lung cancer ($n = 6$). Before AD implantation, all patients needed to report to the hospital ethics committee for approval, and then they were informed of the study procedures and signed informed consent and off-label use consent forms. The demographic and treatment data for the study participants are presented in Table 1 and Table 2. The average follow-up time for all patients was 13.2 months (range: 10–17 months). All 6 patients underwent AD placement with the use of the SFM, and the average duration of operation was 16.17 minutes (16.17 ± 4.67 minutes [mean $\pm$ SD]). Closure was successfully performed in all 6 patients. There were no immediate complications related to the procedure, and all patients were discharged within 24 hours except for patient No. 3, who underwent closure in the ICU (intensive care unit) and had severe pneumonia of the residual right lung. Although this patient was observed to have a significant reduction in air leakage after AD implantation, he eventually died on postoperative day 3 due to complications of severe pneumonia.

Table 1
Patient characteristics and treatment data

Serial number	Sex/Age(year)	Operative site	Disease	Onset time of BPF	Location of BPF	Indwelling time of drainage tube
1	F/73	Lower right lobectomy	Adenocarcinoma	8 months after operation	Right Lower bronchus	2 months
2	M/64	Lower right lobectomy	Squamous cell carcinoma	20 days after operation	Right Lower bronchus	15 days
3	M/66	Left pneumonectomy	Squamous cell carcinoma	9 days after operation	Left Main bronchus	2 months
4	M/71	Upper left lobectomy	Squamous cell carcinoma	40 days after operation	Upper left bronchus	20 days
5	M/70	Right pneumonectomy	Non-small-cell lung cancer	1–2 months after operation [#]	Right main bronchus	23 years
6	M/56	Right middle lobe and right lower lobe lobectomy	Squamous cell carcinoma	1 month after operation	Right middle and lower bronchi	2 months
[#] The patient has been experiencing BPF for 23 years, so it is difficult for him to remember the exact time.						

Table 2
Operation and follow-up information of 6 patients

Serial number	Location of BPF	Fistula diameter	AD model	Duration of operation	Completely blocked	Removed drainage tube	Time from closure to extubation	Follow-up time
1	Right Lower bronchus	10 mm	22-10-24 mm	10 min	Yes	Yes	3 days	17 months
2	Right Lower bronchus	8 mm	16-8-20 mm	15 min	Yes	Yes	3 months	15 months
3	Left Main bronchus	10 mm	23-12-27 mm	18 min	Yes	No	NA	NA
4	Upper left bronchus	8 mm	16-8-20 mm	20 min	Yes	Yes	2 months	12 months
5	Right main bronchus	10 mm	22-10-24 mm	22 min	Yes	Follow-up	NA	12 months
6	Right middle and lower bronchi	Several small fistulas	23-12-27 mm	12 min	No	Yes*	NA*	10 months
# Although patient No. 3 underwent closure in the ICU with respiratory failure was observed to have a significant reduction in air leakage after AD implantation, he eventually died on the third postoperative day due to complications from severe pneumonia.								
* Patient No. 6 underwent thoracoscopic flap sealing after closure failure of AD implantation, and his drainage tube was removed one week after surgery.								

After receiving the occlusion surgery, 5 patients achieved complete occlusion (all except for patient No. 6), and symptoms related to the BPFs disappeared following closure with the AD. Three of 5 patients with complete occlusion removed the thoracic drainage tube. Patient No. 6 whose bronchoscopy showed multiple micro fistulas at the end of the right middle bronchus received AD closure, but we observed persistent air leakage in the water seal drainage bottle at 6 months after AD implantation. Finally, the patient underwent thoracoscopic free anterolateral thigh flap sealing, and his drainage tube was removed one week after surgery. No patients died due to operation complications and BPF recurrence.

Follow-up evidence showed a definite blocking effect of AD placement improvement of patient symptoms. The first improvement after AD placement was reduced in phlegm volume, followed by reduced cough symptoms. After 3 months of follow-up, improvements in the overall condition, such as improvements in exercise tolerance, weight gain, improved stomach intake, and a more positive attitude, were often observed. Representative figures of study patients are presented in Figs. 3–4. # Although patient No. 3 underwent closure in the ICU with

respiratory failure was observed to have a significant reduction in air leakage after AD implantation, he eventually died on the third postoperative day due to complications from severe pneumonia.

* Patient No. 6 underwent thoracoscopic flap sealing after closure failure of AD implantation, and his drainage tube was removed one week after surgery.

Discussion

We present an innovative method (SFM) for AD implantation for the first time and indicate its feasibility and advantages in clinical practice. Six BPF patients who were suitable for AD implantation were screened, all patients underwent AD placement with the use of SFM, and no cases failed. The advantages we observed with SFM over other methods include easy steps, short operation time, few complications, and ease of reaching the fistula for closure. In our shortest implantation, the whole operation only lasted 10 minutes (Patient No. 1 in Table 2). Postoperative CT showed that the accuracy of AD implantation with SFM was also favorable (Fig. 2). Previous studies have reported one case of failed implantation¹³. In this case, AD fell into the pleural cavity, and the cause may be related to severe infection around the fistula. It is not easy to accurately place an AD into the fistula, especially for fistulas in the upper lobe, which are hard to reach. Tedde ML reported a case with right upper lobe BPF who received AD implantation introduced by sheath which was advanced over the guidewire in the working channel in a 60-minute procedure¹⁷. In our study, patient No. 4 was a patient with an upper left BPF, and AD implantation required 20 minutes (Patient No. 4 in Table 2). Few scholars have previously presented data on duration of operation, so the average time for AD implantation could not be found as a reference. However, according to the description of operation procedures, such as the need for rigid bronchoscopy or bronchography performance, it is difficult to imagine that the duration of operation is less than 30 minutes. The shorter duration of operation reduces the risk of mechanical ventilation and anesthesia, which is more meaningful for the safety of AD implantation and reducing complications. The disadvantage of SFM is that the requirement of the bronchoscopy working channel should be 2.8 mm or larger so that the folded AD can be received smoothly. If one wants to place an AD with a large size (for example, 25-14-29 mm or the one described above), the diameter of the AD after folding may be greater than 2.8 mm, which is not suitable for SFM. Additionally, different brands of ADs may have variations in size after folding, which would require attention when operating. In terms of safety, our observations are consistent with previous studies. The technique employed was well tolerated by the patients, with no severe side effects or complications.

Conclusion

In general, the application prospect of ADs in BPF patients is quite optimistic due to the unique advantages and characteristics of ADs. Meanwhile, as a minimally invasive and effective method, the SFM for AD implantation was safe, convenient and worth spreading.

Abbreviations

BPF
bronchopleural fistula;
AD
Amplatzer device;

SFM
Sheath-free method;
EBVs
Endobronchial Valves

Declarations

Ethics approval and consent to participate

We have obtained the written consent from the patient and Ethics Committee of Sir Run Run Shaw Hospital.

Consent for publication

The authors declare that they agreed to publish the uploaded video.

Availability of data and materials

The data and materials in the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no potential conflicts of interest.

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Authors' contributions

JS Z developed the algorithm. HH H carried out most of the analyses. L X participated in the design of the study and helped algorithm development. S X and FJ W drafted the manuscript. JH Z and EG C conceived and coordinated the study. All authors read and approved the final manuscript.

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Figures

Figure 1

ADs used for bronchoscopic closure of bronchopleural fistulas.

A

B

C

Figure 2

Procedures of the Sheath-free method. A, Guide wire entry through the working channel. B, AD connected to the guide wire. C, AD integrated into the working channel.

Figure 3

Bronchopleural fistula following left upper lobe lobectomy in patient No. 4. A, Chest CT before AD implantation. B, Bronchoscopy before AD implantation. C, Bronchoscopy after AD implantation. D, Chest CT after 1 month of AD implantation. E, Water seal drainage bottle was changed to a drainage pack after 1 month of AD implantation. F, Chest CT after 2 months of AD implantation, and the drainage tube was removed after CT scan.

Figure 4

Bronchopleural fistula following right middle lobe and right lower lobe lobectomy in patient No. 6. A, Bronchoscopy before AD implantation. B, Bronchoscopy after AD implantation.

Supplementary Files

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